The 505(B) 2 New Drug Application – A Rapid Drug Approval Pathway

The 505(B)2 regulative is the pathway considered as NDA investigation rule and it comes under "**The Federal Food Drug and Cosmetics Act"**. These rules are like protocols for being relied upon to approve the products formulated by applicants. For the same, applicants need not to obtain a right of reference.

The **505(B) 2** NDA is not similar to an abbreviated NDA (ANDA; described under Section 505(j) of the Act) that contains information to demonstrate the proposed product so it will be identified as a previously approved product. There is no need of clinical as well as pre-clinical trials when you are undergoing the process of approval ANDA that further affects the bi-equivalency test of products.

The approval route of 505(B) 2 can be settled for number of products representing the required and limited changes for the drug items those are previously approved. The following are examples of changes those should be approved in drugs, which would be appropriate to submit as 505(B) 2 applications:

- Changes in dosage form, intensity, route of governance, preparation, dosing regime, or denotation
- A new combination of product where the active ingredients have been previously approved
- Change to an active ingredient that may be like different salt, chelate, ester complex, etc
- New molecular entity when studies have been conducted by other sponsors and published information is pertinent to the application (e.g., a pro-drug or active metabolite of an approved drug)
- Transmission of procedure from Rx indication to an OTC indication
- OTC monograph drug changes are also not adoptable
- Drugs with naturally derived or recombinant (i.e. biological) active ingredients where additional limited clinical data is necessary to show the ingredient is the same as the ingredient in the reference drug Regulatory Professionals, Inc.
- Bioinequivalence of these drug products will be listed for additional studies. It is helpful to know about rates and efficiency as well as safety of the product

The 505(B) 2 act does not applicable for the products:

- Products under Section 505(j)
- Products showing lower extent of absorption over reference drug
- Products having unintended lower rate of absorption in comparison to reference drug

In this way, 505(b) act has its own importance for recognizing the validation and approval of drugs.

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